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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,305

04/08/2004

William Andrew Wilson

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03/17/2005

MCKEE, VOORHEES & SEASE, P.L.C.

ATTN: PIONEER HI-BRED

801 GRAND AVENUE, SUITE 3200

DES MOINES, IA 50309-2721

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,305

Applicant(s)

WILSON ET AL.

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-10 are pending and are under consideration.

Specification

The disclosure is objected to because of the following informalities: for example, page 70, line 14 of the second full paragraph, of the specification contains an embedded hyperlink directed to an Internet address. The use of hyperlinks and/or other form of browser- executable code are not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser- executable code. See MPEP 608.01.

Claim Rejections - 35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because the F1 hybrid maize seed lacks antecedent basis in claim 1. Dependent claim 3 is included in the rejection

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an F1 hybrid seed produced by crossing a plant of the maize inbred line PH8CW with a different maize plant, wherein said F1 hybrid seed comprises at least one set of chromosomes of the maize inbred line PH8CW. The claims are also drawn to maize and plant part produced by growing said F1 hybrid seed. In contrast, Applicant describes inbred maize line PH8CW having specific combination of genotypic and phenotypic characteristics that distinguish the line from other corn lines. Applicant also describes few F1 hybrid seed/plants of PH8CW for performance comparison with known hybrids. However, it is unclear if the seed of said F1 hybrids of the inbred PH8CW have been deposited and are publicly available. These are genus claims.

The Federal Circuit court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). The court also stated "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material". *Id.* Further, the court stated that to adequately describe a claimed genus, Applicant must describe a

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representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus". Id.

Applicant has not described the morphological and/or genotypic characteristics for all hybrid corn plants and seeds produced by crossing the inbred maize line PH8CW with another unidentified maize plant. No specific morphological or genotypic characteristics that distinguish the claimed hybrid corn plants/seeds from other corn plants and seeds are described. The only description recited in the claims is that the hybrid comprises at least one set of chromosomes from inbred PH8CW. This at least one set of chromosomes are unknown because inbred PH8CW is not genotypically described. In addition, this description is insufficient to provide a distinguishing characteristics, given that all hybrids comprise at least one set of chromosomes from one of its parents. Furthermore, variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one non-PH8CW parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-PH8CW inbred parent. As a result, the complete genomic structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ. The phenotypic characteristics of the hybrid depends on how each allelic product interacts with the corresponding allelic product inherited from the other genome, as well as how each gene product interacts with the other gene products in the genome. Given that a claimed hybrid corn plant comprises a set of alleles inherited from each parent and these two sets of alleles interact in a variety of ways to determine the hybrids

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morphological and physiological traits, one cannot correlate the alleles inherited from PH8CW alone, with the phenotype of the hybrid progeny. Therefore, the deposit of PH8CW seeds is insufficient to provide an adequate written description of all hybrid progeny that may be produced by crossing PH8CW plants with second, distinct corn plants.

Tables 3A-3F describe the performance comparison of few hybrids of PH8CW with prior art hybrids. However, these hybrids are not representative species, given the large genus claimed and the variation expected among the hybrids. Table 4 of the specification lists SSRs profiles of inbred PH8CW. Applicant asserts that these SSRs can be used to identify all F1 hybrids having inbred PH8CW as one of their parents. However, while all claimed F1 hybrids would inherit the SSR marker profile of PH8CW, they will inherit the same genetic markers from the second parents as different parents will have different markers. The SSRs of the non-PH8CW parents are not described. In addition, the instant specification does not describe the sequences of the primers that were used to produce these SSRs.

Given the vast number of hybrids encompassed by the claims; the substantial variation in phenotypes expected among these hybrids; and the vast number of unidentified non-PH8CW involved in the breeding, the disclosure of a single hybrid of the inbred PH8CW will not provide adequate written description for all F1 hybrids from inbred PH8CW.

Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See Written Description

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Requirement published in Federal Registry/Vol.66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

Remarks

The claims are deemed free of the prior art, given that the prior art does not teach or fairly suggest a hybrid maize seed/plant produced from the inbred maize PH8CW, wherein the hybrid comprises at least one set of chromosomes of inbred PH8CW.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/4/05
Mai

Medina A. Ibrahim

MEDINA A. IBRAHIM
PATENT EXAMINER